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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/650,799

08/29/2003

Patricia B. Hoyer

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7590

10/27/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

NOTIFICATION DATE

DELIVERY MODE

10/27/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/650,799	Applicant(s) HOYER ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 69-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 08/29/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply filed on 06/30/2008 is acknowledged. Claims 1-68 are cancelled. Claims 69-94 are added, are pending and are under consideration in the instant office action.

Information Disclosure Statement

Applicant states that a copy of the poster listed as reference AAJ at page 4 of the IDS dated 06/07/2007 was submitted with the reply dated 02/19/2008. The poster submitted 02/19/2008 is not a legible copy of the poster submitted 06/07/2007 but appears to be a different poster, (dated 2005 or later). The poster that should be considered for its relevance as art under 35 USC 102(a) and was listed on the IDS filed 06/07/2007 is titled "An ovary-intact mouse model that Mimics Perimenopause in Women".

The information disclosure statement filed 06/17/2008 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 69-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that “No amendment shall introduce new matter into the disclosure of an application after the filing date of the application”.

Claim 69 required a complete depletion of ovarian primordial follicles. Claim 83 is directed to a method of making the animal of claim 69.

The specification provides no implicit or explicit support for a complete depletion of primordial follicles. The specification has only provided support for partial depletion of ovarian follicles expression of the DNA construct in the context of the claimed transgenic mouse. Page 12, lines 13-14 mentions a complete absence of primordial follicles, however, the specification does not associate this effect as having been obtained in the claimed animals. Treatments to obtain complete depletion of primordial follicles required greater amounts of VCD than that claimed (see pages 17-18 and Figures 1-2). Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3rd paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes “If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or

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terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes “When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not “new matter” is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure* [or point to case law supporting incorporation of such a limitation as in the instant case]” (emphasis added).

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 23,25,28-30,37 and 40-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is rendered moot by Applicant’s cancellation of the claim. However, the rejection now applies to newly added claims 86-90 as set forth below.

Claims 83-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 83 is unclear because, while referring to claim 69, it is drawn to a method and claim 69 is drawn to a product. Thus, the claim fails to relate back to the preamble in a positive process in that it does not require that any particular animal be obtained. It is not known whether the characteristics of menopause and/or perimenopause are required for the method.

Claims 84-85 depend from claim 83.

Claim 86 is unclear because the method steps fail to relate back to the preamble in a positive process. The claim does not recite what is indicative of the desired outcome or what assay should be performed to complete the method.

Claims 87-90 depend from claim 86.

Claim 91 is unclear because the method steps fail to relate back to the preamble in a positive process. The claim does not recite what is indicative of the desired outcome. It is not clear what a limit on the size of a population is required. The claim fails to provide a nexus between having at least partial ovarian failure and control of population size.

Claims 92-94 depend from claim 91.

Claims 88 and 93 are unclear because it is not apparent how the claims further limit the subject matter of the parent claims 86 and 91. Claims 88 and 93 each require administering VCD at a dosage of 100 mg/kg/day, which is required by each of claims 86 and 91

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1) The rejection of claims 1,4,5,9-12,13, and 20 under 35 U.S.C. 102(b) as being anticipated by Kao et al (1999, IDS) as evidenced by Amant [2001, **Circulation**, 104:2576-2581] and Osei-Hyiaman (1998, **Am Jour Epidem**, 148:1055-1061) is rendered moot by Applicant's cancellation of the claims. Newly added claim 69 is directed to the same subjection matter as previous claim 1 with the exception that a complete depletion of ovarian primordial follicles is required. This phenotype differs from that observed by Kao, who administered 80 mg/kg/day and thus, Kao does not teach the limitations of newly added claim 69. However, the specification fails to support such a complete depletion (see above). Thus, it is not conceded that Kao does not teach a mammal that would result from administration of 100 mg/kg/day VCD, but Kao does not teach that complete follicle depletion would occur.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1) The rejection of claims 1 and 21 under 35 U.S.C. 103(a) as being unpatentable over Kao et al (1999, IDS) in view of Abel *et al.* (Jour Clin Endocrin Metab, 84:2111-2118, 1999) and further in view of Judd (1976, IDS) is rendered moot by Applicant's cancellation of the claims. Newly added claim 69 is directed to the same subjection matter as previous claim 1 with the exception that a complete depletion of ovarian primordial follicles is required. Claim 69 is free of the art as set forth in the preceding section (35 USC 102).

2) The rejection of claims 1 and 22 35 U.S.C. 103(a) as being unpatentable over Kao et al (1999, IDS) in view of Mulholland *et al.* (**Jour Urol**, 1982, 127:1010-1013) and further in view of Judd (1976, IDS) is rendered moot by Applicant's cancellation of the claims. Newly added claim 69 is directed to the same subject matter as previous claim 1 with the exception that a complete depletion of ovarian primordial follicles is required. Claim 69 is free of the art as set forth in the preceding section (35 USC 102).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Valarie Bertoglio, Ph.D./
Primary Examiner
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